NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3081. Paramycin Tablets. U. S. v. 1 Bottle, etc. (F. D. C. No. 28754. Sample No. 3372–K.)

LIBEL FILED: March 10, 1950, District of Columbia.

ALLEGED SHIPMENT: On or about February 24, 1950, by the Paramino Corp., from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle and 3 100-tablet bottles of *Paramycin Tablets* at Washington, D. C.

LABEL, IN PART: "Enteric-Coated—0.5 gm. Paramycin Tablets (Para Aminosalicylic Acid) Caution: New drug, Limited by Federal Law to Investigational Use. Sole Distributors Paramino Corporation * * * New York, N. Y."

NATURE OF CHARGE: Section 505 (a), the article was a drug which should not have been introduced or delivered for introduction into interstate commerce since it was a new drug and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: April 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3082. Misbranding of Tuinal Capsules and Benzedrine Sulfate Tablets. U. S. v. The Eagle Drug Co., Leo F. Portman, and John Rundt. Pleas of guilty. Fine of $300 against company, $100 against defendant Portman, and $200 against defendant Rundt, plus costs. (F. D. C. No. 28131. Sample Nos. 19309–K, 51661–K, 51837–K.)

INFORMATION FILED: March 10, 1950, Northern District of Ohio, against the Eagle Drug Co., a corporation, Canton, Ohio, and against John Rundt, president and treasurer, and Leo F. Portman, vice president and secretary, of the corporation.

INTERSTATE SHIPMENT: These drugs were shipped in interstate commerce into the State of Ohio. The *Tuinal Capsules* were shipped from the State of Pennsylvania and the *Benzedrine Sulfate Tablets* from the State of Indiana, prior to the dates of the sales referred to below.

ALLEGED VIOLATION: On or about January 26, May 23, and June 8, 1949, while the drugs were being held for sale after shipment in interstate commerce, the Eagle Drug Co. and John Rundt caused certain quantities of the *Tuinal Capsules* and *Benzedrine Sulfate Tablets*, and the Eagle Drug Co. and Leo F. Portman caused a quantity of the *Tuinal Capsules*, to be repackaged and sold to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "1½ grs.," borne on the label of a portion of the repackaged *Tuinal Capsules*, was false and misleading since the capsules contained more than 1½ grs. of the drug; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *Tuinal Capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the *Tuinal Capsules* involved